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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,691	05/24/2004	Itzhak Bentwich	050992.0400.01USCP	3690
37808	7590	07/23/2009		
ROSETTA-GENOMICS c/o PSWS 700 W. 47TH STREET SUITE 1000 KANSAS CITY, MO 64112			EXAMINER WOLLENBERGER, LOUIS V	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 07/23/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/709,691	<b>Applicant(s)</b> BENTWICH ET AL.	
	<b>Examiner</b> Louis Wollenberger	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23, 25, 31, 33, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 is/are allowed.
- 6) ☒ Claim(s) 23, 31, 33, and 39 is/are rejected.
- 7) ☒ Claim(s) 40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 5/12/2009 have been considered. Rejections and/or objections not reiterated from the previous office action mailed 2/12/2009 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendments to the claims filed 5/12/2009 are acknowledged. With entry of the amendment, Claims 23, 25, 31, 33, 39, and 40 are pending and under consideration.

### ***Specification***

The application contains disclosure entirely outside the bounds of the allowed claims. Applicant is required to modify the brief summary of the invention and restrict the descriptive matter so as to be in harmony with the claims (MPEP § 1302.01).

In the instant case the specification incorporates by reference several large tables, Tables 1-11, submitted to the Office in the form of compact discs, which, altogether, are said by applicant to contain several thousand kilobytes of information, the large majority of which is not pertinent to the claimed invention: SEQ ID NO:348 and 4233864.

Using the conversion factor set forth in 37 CFR 1.52(f)(1), the electronic information contained in Tables 1-11 represents tens if not hundreds of thousands of sheets of additional disclosure beyond the approximately 162 pages of paper copy specification filed therewith. A review of Tables 1-11 finds the tables disclose information directed to hundreds of thousands of different nucleotide sequences that have no disclosed relation to the claimed sequences.

In addition to the requirement under MPEP 1302.01, Applicant is required under 37 CFR 1.52(e)(5) to amend the specification to include in the paper portion of the specification all descriptive matter pertinent to SEQ ID NO:348 and 4233864 that was previously submitted in tables on compact disc. Amendments to the specification must comply with 37 CFR 1.121 and 1.125.

***Claim Objections***

Claims 33 and 40 are objected to because of apparent typographical errors: "heterolgous" and "heterlogous."

***Claim Rejections - 35 USC § 101 and 112, First Paragraph—withdrawn***

The rejection of Claims 23, 25, 31, and 33 under 35 U.S.C. 101 and 35 USC 112, first paragraph, because the claimed invention is not supported by a credible asserted utility or a well established utility is withdrawn in view of the totality of evidence of record.

***Claim Rejections - 35 USC § 102—maintained***

Claim 31 remains rejected and new claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al. GenBank Accession No. AZ593982, published online at NCBI on December 13, 2000 is withdrawn in view of the amendment to the claim.

As shown by the alignment below, Dunn et al. taught a vector comprising a sequence encoding and complementary to SEQ ID NO:348. Accordingly, the prior art disclosed the instantly claimed vector. The vector disclosed by Dunn et al. is indistinguishable from the probe (i.e., nucleic acid) defined by claim 39 and would be capable of being used as a probe.

Art Unit: 1635

```
>[A2592982.1] 1M0405M14R Mouse 10kb plasmid UUGClM library Mus musculus genomic
clone UUGClM0405M14 R, genomic survey sequence.
Length=791
```

```
Score = 152 bits (82), Expect = 1e-34
Identities = 88/91 (96%), Gaps = 0/91 (0%)
Strand=Plus/Plus
```

```
Query 1 CCTGCTCCCGCCCCAGCAGCACACTGTGGTTTGTACGGCACTGTGGCCACGTCACAAACCA 69
      ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||
Sbjct 29 CCTGCCCCCGCCCCAGCAGCACACTGTGGTTTGTACGGCACTGTGGCCACGTCACAAACCA 88

Query 61 CACTGTGGTGTGTAGAGCGAGGGTGGGGGAGG 91
      ||||| ||||| ||||| ||||| ||||| |||||
Sbjct 89 CACTGTGGTGTGTAGAGCGAGGGTATGGGAGG 119
```

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Claims 31 and 33 remain rejected and new claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Birren et al., GenBank Acc. No. AC015918 “Homo sapiens chromosome 17 clone CTD-316508 map 17”, published online by NCBI on March 27, 2003. (The reference contains a lengthy sequence disclosure. Applicant is provided with the first 3 pages disclosing features relevant to the rejection and a portion of the sequence

As shown by the alignment below, Birren et al. disclosed a human BAC clone (i.e., vector) comprising a sequence encoding and complementary to instant SEQ ID NO:348 and 4233864. The vector disclosed by Birren et al. is indistinguishable from the probe (i.e., nucleic acid) defined by claim 40 and would be capable of being used as a probe. Accordingly, Birren et al. anticipates the instant claims.

Art Unit: 1635

```
>gb|A2592982.1| 1M0405M14R Mouse 10kb plasmid UUGClM library Mus musculus genomic
clone UUGClM0405M14 R, genomic survey sequence.
Length=791
```

```
Score = 192 bits (82), Expect = 1e-34
Identities = 88/91 (96%), Gaps = 0/91 (0%)
Strand=Plus/Plus
```

```
Query 1 CCTGCTCCCGCCCCAGCAGCACACTGTGGTTTGTACGGCACTGTGGCCACGTCCAAACCA 60
      ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||
Sbjct 29 CCTGCCCCCGCCCCAGCAGCACACTGTGGTTTGTACGGCACTGTGGCCACGTCCAAACCA 88

Query 61 CACTGTGGTGTATTAGAGCGAGGGTGGGGGAGG 91
      ||||| ||||| ||||| ||||| |||||
Sbjct 89 CACTGTGGTGTATTAGAGCGAGGGTATGGGAGG 119
```

```
>gb|AC015818.181 ||| Homo sapiens chromosome 17 clone CTD-316508 map 17, 21 unordered
pieces
Length=220581
```

```
Score = 169 bits (91), Expect = 2e-39
Identities = 91/91 (100%), Gaps = 0/91 (0%)
Strand=Plus/Minus
```

```
Query 1 CCTGCTCCCGCCCCAGCAGCACACTGTGGTTTGTACGGCACTGTGGCCACGTCCAAACCA 60
      ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||
Sbjct 40348 CCTGCTCCCGCCCCAGCAGCACACTGTGGTTTGTACGGCACTGTGGCCACGTCCAAACCA 40289

Query 61 CACTGTGGTGTATTAGAGCGAGGGTGGGGGAGG 91
      ||||| ||||| ||||| ||||| |||||
Sbjct 40288 CACTGTGGTGTATTAGAGCGAGGGTGGGGGAGG 40258
```

### *Response to Arguments*

Applicant argues the vectors of claims 31 and 33 contain inserts that are smaller in length than those disclosed in the cited references, and the cited references teach no other insert except the 701 and 220,581 sequences. However, the instant claims do not recite inserts and are not limited to the specifically recited "heterologous" sequences. The claims are drawn to vectors comprising a heterologous sequence. Thus, vectors according to the claims may include (and do not exclude) additional, unrecited heterologous sequences (MPEP 2111.03).

***Claim Rejections - 35 USC § 103—withdrawn***

The rejection of Claims 23 and 25 under 35 U.S.C. 103(a) as being unpatentable over Birren et al., GenBank Acc. No. AC015918 “Homo sapiens chromosome 17 clone CTD-316508 map 17”, published online by NCBI on March 27, 2003, as applied to claims 31 and 33 above in view of:

1. Venter et al. (US Patent 6,812,339)
2. Buck et al. (Biotechniques (1999) 27(3): 526-538);
3. Hogan (US Pat. 5,541,308, July 30, 1996); and
4. Brown (1998) “In situ hybridization with riboprobes: An overview for veterinary pathologists” *Vet. Pathol.* 35:159-167

is withdrawn in view of Applicant’s arguments, which are found persuasive.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou (US Patent 7,250,289).

Zhou disclosed and claims arrays comprising a plurality of 25-nucleotide nucleic acid probes. Methods for synthesizing (i.e., isolating) and using each probe in the array are disclosed. One probe, SEQ ID NO:669995, is at least 80% identical/complementary to instant SEQ ID NO:348 and its complements, as defined by claim 23, parts c and d (see alignment below). Zhou taught that nucleic acids of their invention may range from at least 2 to preferably at least 8, 15 or 20 nucleotides in length (col. 6 and elsewhere). At column 8, it is taught the nucleic acids spotted onto the array can be essentially of any length from 1 to 1000 monomers. Accordingly, one of skill would reasonably have envisioned nucleic acid probes of at least 8 to 25 nucleotides in length corresponding to any of the disclosed nucleic acid probes, including SEQ ID NO: 669995. One of skill would reasonably have been led to make and use any of these probes because Zhou states that any probe of any length, including those lengths specifically suggested, may be used on the array. One would reasonably expect the 24-mer or 23 mer equivalents of SEQ ID NO: 669995, or any other probed disclosed therein, to have substantially the same hybridization properties as SEQ ID NO: 669995, and would reasonably be motivated to make and use shorter nucleic acids for economy. 24-mer or even 23 mer equivalents of SEQ ID NO: 669995 necessarily include sequences at least 80% identical/complementary to instant SEQ ID NO:348, DNA encoding SEQ ID NO:348, and complements thereof. Accordingly, the instantly claimed sequences would have been prima facie obvious.



Art Unit: 1635

```
RESULT 6
US-10-719-900-669995/c
; Sequence 669995, Application US/10719900
; Patent No. 7250289
; GENERAL INFORMATION:
; APPLICANT: Xue Mei Zhou
; TITLE OF INVENTION: Methods of Genetic Analysis of Mouse
; FILE REFERENCE: 3528.1
; CURRENT APPLICATION NUMBER: US/10/719,900
; CURRENT FILING DATE: 2003-11-20
; PRIOR APPLICATION NUMBER: 60/427,808
; PRIOR FILING DATE: 2002 11 20
; NUMBER OF SEQ ID NOS: 982914
; SOFTWARE: Microarray Probe Sequence Listing Generator V 1.1
; Patent No. 7250289
; SEQ ID NO 669995
; LENGTH: 25
; TYPE: DNA
; ORGANISM: Mus musculus
US-10-719-900-669995

Query Match          70.9%; Score 15.6; DB 5; Length 25;
Best Local Similarity 68.2%; Pred. No. 9.1e+02;
Matches 15; Conservative 3; Mismatches 4; Indels 0; Gaps 0;

Qy      1 CAGCAGCACACUGUGGUUGUA 22
        ||||| ||||| |:| : :|
Db      23 CAGCAGCACACAGTGGACTCTA 2
```

### *Conclusion*

Claim 25 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/  
Primary Examiner, Art Unit 1635  
July 17, 2009